K071500

510(k) Summary

Nano-Bond II Adhesive System

AUG 10 2007

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Pentron Clinical Technologies, LLC 53 North Plains Industrial Road Wallingford, CT 06492 Telephone 1 (203) 303-2280 Fax 1 (203) 284-4986
Official Contact:	Greg Moreau
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone 1 (858) 792-1235 Fax 1 (858) 792-1236 email: flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Nano-Bond II Adhesive System
Common Name:	Resin, dental cement
Classification Name:	Resin tooth bonding agent, dental cement
Classification Regulations :	(21 CFR 872.3200, 872.3275) Class II
Product Codes:	KLE, EMA
Classification Panel:	Dental Products
Reviewing Branch:	Dental Devices

ESTABLISHMENT REGISTRATION

Establishment Registration Number:	3003690896
Owner/Operator Number:	9050352

INTENDED USE

Nano-Bond II Adhesive System is used for the adhesion of dentin to various polymeric filling materials (composites) and used with other conditioners or combination of conditioners for bonding composite to metal including amalgam, gold, semi-precious and non-precious alloys, porcelain and glass and luting of same to dentin and enamel.

K071500

DEVICE DESCRIPTION

Nano-Bond II Adhesive System is a light-cured, reinforced dentin bonding agent. It is provided in a kit containing two components, Nano-Bond Self-Etch Primer and Nano-Bond II Adhesive and an optional component, Nano-Bond II Dual Cure Activator. The components also are available individually as refills.

EQUIVALENCE TO MARKETED PRODUCT

Pentron Clinical Technologies, LLC submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, Nano-Bond II Adhesive System is substantially equivalent in indications and design principles to the following predicate device which has been determined by FDA to be substantially equivalent to preamendment devices: Nano Bond (Bond-3 Adhesive) (K020499) from Jeneric/Pentron, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2007

Pentron Clinical Technologies, LLC
C/O Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K071500
Trade/Device Name: Nano-Bond II Adhesive System
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE, EMA
Dated: May 25, 2007
Received: May 31, 2007

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071500

Device Name: Nano-Bond II Adhesive System

Indications for Use:

Nano-Bond II Adhesive System is used for the adhesion of dentin to various polymeric filling materials (composites) and used with other conditioners or combination of conditioners for bonding composite to metal including amalgam, gold, semi-precious and non-precious alloys, porcelain and glass and luting of same to dentin and enamel.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071500